DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2015

Zimmer Spine, Incorporated
Ms. Donna M. Semlak
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K142752
Trade/Device Name: Minit® Posterior Cervical-Thoracic Fixation System, Nex-Link® Spinal Fixation System, Nex-Link OCT® Cervical Plating System, Sequoia® Pedicle Screw System including SpeedLink II™, ST360º® Spinal Fixation System, and Title® 2 Polyaxial Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, MNI, MNH
Dated: May 18, 2015
Received: May 19, 2015

Dear Ms. Semlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142752

Device Name
Minit(R) Posterior Cervical-Thoracic Fixation System

Indications for Use *(Describe)*
When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the Endius Minit Posterior Cervical and Upper Thoracic Fixation System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and Rods
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Screws/Connectors
The use of screws is limited to placement in the TI-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

Axial and Offset Rod Connectors
The Minit Posterior Cervical and Upper Thoracic Fixation System can also be linked to the TiTLE and TiTLE 2 System offered by Endius Inc. using the Axial Rod Connectors, Dual Rod Connectors and the Tri Screw Dual Rod Connectors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142752

Device Name
Nex-Link(R) Spinal Fixation System

Indications for Use *(Describe)*
When intended to promote fusion of the cervical spine and the thoracic spine, (Cl-T3), the NexLink Spinal Fixation System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (Cl-T3) spine. The use of multiaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. The multiaxial screws are not intended to be placed in the cervical spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K142752

Device Name
Nex-Link OCT(R) Cervical Plating System

Indications for Use *(Describe)*
The NexLink OCT Occipital Cervical Plating System is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies), spondylolisthesis, spinal stenosis, fracture/dislocation, atlantoaxial fracture with instability, occipito-cervical dislocation, revision of previous cervical spine fusion surgery and tumors.

The Cancellous and Cortical Bone Screws (3.5mm and 4mm diameters; 6mm-20mm threaded lengths) are used with the NexLink OCT Occipital Cervical Plating System to allow for occipital fixation and limited to occipital fixation only. The 4mm Cannulated Side Loading Closed Screws are limited to placement in the upper thoracic spine (T1-T3) for additional stabilization of the cervical spine for the indications specified above.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K142752

Device Name
Sequoia(R) Pedicle Screw System including SpeedLink II(TM)

Indications for Use *(Describe)*
When intended for pedicle screw fixation from T1–S1, the Sequoia Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

When used as a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after the solid fusion is established.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1-S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degenerative of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion.

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142752

Device Name
ST360º(R) Spinal Fixation System

Indications for Use *(Describe)*
The ST360º Spinal Fixation System is intended for posterior, non-cervical pedicle and nonpedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

When used as a sacral screw system, the ST360º Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined as chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic, deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the ST360° Spinal Fixation System are intended for the sacral iliac attachment only. Transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for sacral screw fixation of this system are T1 to the sacrum.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142752

Device Name
Title(R) 2 Polyaxial Spinal System

Indications for Use *(Describe)*
The TiTLE 2 Polyaxial Spinal System is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The TiTLE 2 Polyaxial Spinal System is a Pedicle Screw System intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The TiTLE 2 Polyaxial Spinal System is also indicated for pedicle screw fixation for severe spondylolisthesis (grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

In addition, TiTLE 2 Polyaxial Spinal System, when not used with pedicle screws, is indicated for sacral screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis, and kyphosis), tumor, fracture, and previous failed fusion surgery.

The TiTLE 2 Polyaxial Spinal System can also be linked to the Minit® Posterior Cervical and Upper Thoracic Fixation System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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	510(k) SUMMARY ***Pedicle Screw-Rod Systems***

Date of Summary Preparation: May 18, 2015

Submitter:
Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439
USA

Establishment Registration Number: 2184052 (Minneapolis)

Company Contact (Primary):
Donna M. Semlak
Senior Regulatory Affairs Specialist
Email: Donna.Semlak@zimmer.com
Office: 952.857.5643
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Common Name(s): Pedicle Screw-Rod Systems

Device/Trade Names(s*):*
Minit® Posterior Cervical-Thoracic Fixation System
Nex-Link® Spinal Fixation System
Nex-Link OCT® Cervical Plating System
Sequoia® Pedicle Screw System including *SpeedLink II*™
ST360°® Spinal Fixation System
Title® *2* Polyaxial Spinal System

Device Classification: Class III / II

Regulation Number and Product Code(s):
21 CFR § 888.3050 / KWP
Orthosis, Fixation, Spinal Interlaminal
21 CFR § 888.3070 / MNI / MNH
Orthosis, Spinal Pedicle Fixation
21 CFR § 888.3070 / NKB
Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease

Predicate Devices:

The primary predicate device for this submission is the currently marketed *Zimmer Spine ST360 Spinal Fixation System* listed below. The purpose of this submission is to update product specific package inserts (IFU) with MRI Conditional language only.

Product Name	FDA 501(k) or PMA Numbers	Classification	Primary Code
ST360	K133291	Class III / II	NKB 21 CFR § 888.3070

Additional Predicate Devices:

Product Name	FDA 501(k) Numbers	Classification	Primary Code
Minit	K070282	Class III / II	NKB 21 CFR § 888.3070
	K060683	Class II	KWP 21 CFR § 888.3050
NexLink	K062505	Class II	MNI 21 CFR § 888.3070
	K060634		
	K052566		
	K052247		
	K031985		
NexLink OCT	K090060	Class II	KWP 21 CFR § 888.3050
Sequoia (Speedlink)	K131980	Class III / II	NKB 21 CFR § 888.3070
Title 2 (Northstar)	K133086	Class III / II	NKB 21 CFR § 888.3070

There are no reference devices for this submission.

General Device Description:

The Zimmer Spine Pedicle Screw-Rod System implants include pedicle, poly-axial or fixed screws of varying diameters and lengths, rods of varying lengths, hooks (anchors) in varying designs and fixed and adjustable transverse connectors (cross-links)

These implants are manufactured from medical grade Ti-Al-4V ELI titanium alloy and or commercially pure titanium. The system(s) are provided to the end-user Non-Sterile. Implants and instrumentation are provided clean and must be sterilized prior to use by the end-user. The system(s) implants are designed for single-use only

The purpose of this submission was to demonstrate through testing and engineering analyses that the subject devices can be labeled as MR Conditional.

Indications for Use:

System	Indications for Use
Minit® Posterior Cervical-Thoracic Fixation System	When intended to promote fusion of the cervical spine and the thoracic spine, (CIT3), **the** Endius Minit Posterior Cervical and Upper Thoracic Fixation System is indicated for the following: **DDD** (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors. Hooks and Rods The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation **or** trauma in the cervical/upper thoracic (C1-T3) spine. Screws/Connectors The use of screws is limited to placement in the TI-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine. Axial and Offset Rod Connectors The Minit Posterior Cervical and Upper Thoracic Fixation System can also be linked to the TiTLE and TiTLE 2 System offered by Endius Inc. using the Axial Rod Connectors, Dual Rod Connectors and the Tri Screw Dual Rod Connectors.
Nex-Link® Spinal Fixation System	When intended to promote fusion of the cervical spine and the thoracic spine, (C l-T3), the NexLink Spinal Fixation System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors. Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C l-T3) spine. The use of multiaxial screws is limited to placement in T l-T3 in treating thoracic conditions only. The multiaxial screws are not intended to be placed in the cervical spine.
Nex-Link OCT® Cervical Plating System	The NexLink OCT Occipital Cervical Plating System is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies), spondylolisthesis, spinal stenosis, fracture/dislocation, atlantoaxial fracture with instability, occipito-cervical dislocation, revision of previous cervical spine fusion surgery and tumors. The Cancellous and Cortical Bone Screws (3.5mm and 4mm diameters; 6mm-20mm threaded lengths) are used with the NexLink OCT Occipital Cervical Plating System to allow for occipital fixation and limited to occipital fixation only. The 4mm Cannulated Side Loading Closed Screws are limited to placement in the upper thoracic spine (T1-T3) for additional stabilization of the cervical spine for the indications specified above.
Sequoia® Pedicle Screw System including *SpeedLink II*™	When intended for pedicle screw fixation from T1 –S1, the Sequoia Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion. As pedicle screw system places between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after the solid fusion is established. When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1-S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degenerative of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion.

System	Indications for Use
	After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.
ST360º® Spinal Fixation System	The ST360º Spinal Fixation System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients. When used as a sacral screw system, the ST360º Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined as chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic, deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the ST360° Spinal Fixation System are intended for the sacral iliac attachment only. Transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for sacral screw fixation of this system are T1 to the sacrum.
Title® *2* Polyaxial Spinal System	The TiTLE 2 Polyaxial Spinal System is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine. The TiTLE 2 Polyaxial Spinal System is a Pedicle Screw System intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The TiTLE 2 Polyaxial Spinal System is also indicated for pedicle screw fixation for severe spondylolisthesis (grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1. In addition, TiTLE 2 Polyaxial Spinal System, when not used with pedicle screws, is indicated for sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis, and kyphosis), tumor, fracture, and previous failed fusion surgery. The TiTLE 2 Polyaxial Spinal System can also be linked to the Minit® Posterior Cervical and Upper Thoracic Fixation System.

Summary of Technological Characteristics:

The technological characteristics remain the same between the subject and predicate devices. There are no changes to the implants (rods and/or screws) and instrumentation within this submission. This submission is only proposing labeling updates regarding interactions with magnetic fields during Magnetic Resonance Imaging (MRI) with respect to patient safety.

Summary of Performance Testing:

Magnetic Resonance Imaging (MRI) testing of screws and rods contained in the *Zimmer Spine Pedicle Screw-Rod Systems* were assessed and tested appropriately to design controls and the following ASTM Standards.

- ASTM F2052: 2006 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119: 2007 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2182: 11a* Standard Test Method of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2213: 2006 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

Conclusion:

Zimmer Spine considers the subject *Zimmer Spine Pedicle Screw-Rod Systems* to be substantially equivalent to the currently marketed (predicate) *Zimmer Spine Pedicle Screw-Rod Systems* listed as above because:

- No changes to the intended use,
- No changes to mechanical and functional performance,
- No changes to the functional scientific technology,
- No changes to the implants (screws or rods),
- No changes to the instrumentation,
- No changes to the technological characteristics mentioned above
- No changes to the surgical technique steps